510(k) SUMMARY
Pollogen Ltd.'s Surgen U System

DEC 18 2013

Applicant's name: Pollogen Ltd.
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Date Prepared: December 18, 2013

Name of Device: Surgen U system

Common or Usual Name: Electrosurgical cutting and coagulation device and accessories

Classification: **Product Code:** GEI
Regulation No: 21 C.F.R. §878.4400
Class: II
Classification Panel: General & Plastic Surgery

Predicate Devices

Invasix Ltd., Fractora (K102461)

Device Description

The Surgen™ U system delivers bipolar radiofrequency (RF) electrical current to the skin surface for dermatological procedures requiring ablation and resurfacing of the skin. The physician can control the parameters of the device through a user interface.

Intended Use / Indications for Use

Pollogen's Surgen U system is intended for dermatological procedures requiring ablation and resurfacing of the skin.

Technological Characteristics

The Surgen U system consists of a console, Hybrid Energy (HE) hand held Applicator, Disposable tips, Footswitch and a Patient–Controlled Manual Switch. The disposable tips

attach to the distal end of the applicator and are placed on the patient's skin for treatment. The tips contain a matrix of bi-polar electrode pins. The disposable tips are provided sterile and in two size options. The applicator and tips are connected to the main console unit by a cable containing electrical wiring and a connector. A Footswitch controls activation of the RF current for delivery through the applicator tips. The physician can control the parameters of the treatment through a touch-screen user interface on the main console control panel. The system also includes a Patient–Controlled Manual Switch for the patient to stop treatment in case of discomfort.

Performance Data

Pollogen conducted several performance tests to demonstrate that the Surgen U system complies with performance standards and that it functions as intended. In this submission bench testing performance data as well as histology data presented.

- Several bench tests were done to support the device performance, HE Electrical Verification was done to validate the Surgen U power control and accuracy in reference to the user's input, and verify the maximum energy per pin is not higher than 62 mJ.

- HE Mechanical verification was done to validate Applicator pins mechanical interface with disposable tip and to validate Applicator HE drop test.

- HE disposable tip drop test Verification was done to validate disposable tip packages durability after drop tests.

- Performance testing of the Hybrid Energy Applicator Tips was done to validate that the HE tips, gen 12 and gen 36, are capable of performing 800 pulses while electrode pins and return were not affected and remain fully intact.

- A pre-clinical study was performed in order to evaluate the safety of Pollogen's HE applicator for fractional skin ablation treatment. For four time points, treatment was applied on animal (pig) skin for each disposable tip. Study results demonstrate that the treatment induces the expected fractional pattern at the treatment site, surrounded by normal healthy tissue. The results of this study support the conclusion that fractional ablation treatment using Pollogen's HE Applicator is safe and effective.

In all instances, the Surgen U system functioned as intended and observations were as expected.

Performance Standards

The Surgen U system complies with the following performance standards:

- EN/IEC 60601-1 Medical Electrical Equipment-Part 1: General Requirements for Safety. Collateral Standard: Safety Requirements for Medical Electrical Systems.

- EN/IEC 60601-1-2 Medical Electrical Equipment Part 1-2: Collateral Standard: Electromagnetic Compatibility – Requirements and Tests.
- EN/IEC 60601-2-2 - Safety of high frequency surgical equipment.

Substantial Equivalence

The Surgen U system is as safe and effective as Invasix Ltd.'s Fractora device (K102461). The Surgen U system has the same intended use and indications for use and similar technological characteristics and principles of operation as its predicate device.
The main output parameter that determines the ablative and coagulative effects is the energy per pin, which is identical for the Surgen U and the predicate device. Minor differences in the number of pins, and array dimensions, may slightly affect the number of pulses required to cover the treatment area.
The minor technological differences between the Surgen U system and its predicate device raise no new issues of safety or effectiveness. Performance data demonstrate that the Surgen U system is as safe and effective as its predicate device. Thus, Surgen U is substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

December 18, 2013

Pollogen Ltd
% Mr. Jonathan S. Kahan
Hogan Lovells US LLP
555 Thirteenth Street, Northwest
Washington, District of Columbia 20004

Re: K131758
Trade/Device Name: Surgen U System
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: November 8, 2013
Received: November 12, 2013

Dear Mr. Kahan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Joshua C. Nipper -S

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K131758

Device Name: Surgen U

Indications for Use: Pollogen's Surgen U system is intended for dermatological procedures requiring ablation and resurfacing of the skin.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Long H. Chen -A

Digitally signed by Long H. Chen -A
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Long H. Chen -A, 0.9.2342.19200300.100.1.1=1300369056
Date: 2013.12.18 13:11:10 -05'00'

for BSA

(Division Sign-off)
Division of Surgical Devices
510(k) Number: K131758